Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2045915	03/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
The Dermasurgery Center, Llc	1245 Camellia Boulevard, Suite 300, Lafayette, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was conducted at The Dermasurgery Center, LLC-CLIA ID # 19D2045915 on March 26, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 1 (who also serves as the Laboratory Director) Personnel 2 Personnel 3 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on March 26, 2019, Personnel 1 stated the laboratory was

	unaware that a competency assessment policy that included the six (6) procedures was needed. Personnel 1 further stated he was unaware it was required since doctors are performing the testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of Mycology testing at least twice annually. Findings: 1. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs KOH preps. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for verification of the accuracy of Mycology testing, KOH preps. 3. In interview on March 26, 2019 at 1:30 pm, Personnel 4 stated the laboratory did not perform peer reviews for KOH preps. Personnel 4 confirmed the laboratory did not verify the accuracy of Mycology testing at least twice annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for the following: a) Twice a year verification for accuracy of Mycology testing to include corrective action plan 2. In interview on March 26, 2019 at 1:30 pm, Personnel 4 confirmed the laboratory did not have the identified policy.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in

	the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies for Mycology testing (KOH preps) that included the following: a) Detailed policies and procedures for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection that meet manufacturer requirements for each specialty and/or instrument b) Step-by-step performance of the procedure, including interpretation of the results 2. In interview on March 26, 2019 at 1:30 pm, Personnel 4 stated the laboratory did not have a written KOH procedure for the Lafayette location.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform annual preventative maintenance per laboratory policy. Findings: 1. Review of the laboratory's maintenance policies revealed the following: a)"Microscope: have one year service contracts performed." b)"Cryostat Yearly Maintenance: Preventative maintenance and grounding checks are done and documented annually" 2. Review of the laboratory's service records revealed the laboratory did not have documentation of annual preventative maintenance (PM) performance for the following: a) Microscope: no documentation of PM for 2017 b) Cryostat: no documentation of PM for 2018 3. In interview on March 26, 2019 at 2:48 pm, Personnel 4 stated the laboratory did not have PM performed in 2018 for the cryostat due to the service tech being hospitalized. 4. In further interview on March 26, 2019 at 3:00 pm, Personnel 4 stated the laboratory did not have documentation of the 2017 PM performance for the microscope.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5217.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5433.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401 and D5403.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5433.